LEGAL HELPDESK

Q&A NO. 026

What are the legal aspects of interoperability of biobanks, across Austria, Europe and worldwide?

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Image provided by Medical University of Graz (BBMRI.at coordinator)

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1. Introduction

COMMENT

"In biobanking, interoperability represents the key to forming national and international research collaborations, which have become an inevitable prerequisite for high throughput medical and human biological research"[1]. To promote the transfer of both data and samples between biobanks in Austria (thus optimising the scientific potential of these valuable resources), within the European Union (hereinafter: EU) and across third countries, it has been pointed out that "[…] sample data needs to be documented in a standardized way to become comparable and searchable"[2]. There are several initiatives dedicated to such standardisation of data samples, such as MIABIS, the *Minimum Information About Biobank data Sharing initiative*[3].

Apart from data management solutions, legal intervention at the regulatory level can help make transfer of samples and data, as well as other aspects relating to biobanking, further streamlined and straightforward, as the current status is that the "[…] regulation of biobanking internationally is highly fragmented and confronts researchers with a maze of laws, guidelines and recommendations that unnecessarily complicate matters"[4]. Informed consent and data and samples access and intellectual property rights are some of the ethical and legal issues dealt with differently in various legal landscapes[5]. This extends also to different ethical and legal considerations being taken into account by Ethics Committees, further hindering applying Findable, Accessible, Interoperable, and Reusable (FAIR) principles to biospecimens and biobanks[6], and especially to the metadata associated with the stored biospecimens. Below, we listed some examples of such regulatory level intervention which can promote biobank interoperability at different levels.

1.1. Within Austria:

- Pursuing uniformised Informed Consent forms for all Austria biobanks: initiatives for the harmonisation of consent forms have been pursued in other EU Member States (MS). Such is the case of Germany where the *Arbeitskreis Medizinischer Ethikkommissionen in der Bundesrepublik Deutschland (AKEK) Arbeitsgruppe Biobanking* provides a series of informed consent templates[7] for adult donors who are able to give their consent; for minors of various age groups (12-17 and 7-11) and their parents/guardians; and for the collection of biomaterials for use outside the trial protocol during a clinical drug trial;

[1] KIEHNTOPF, M., & KRAWCZAK, M. (2011). Biobanking and international interoperability: samples. *Human genetics*, *130*, pp. 369-376, p. 369.

[2] Swiss Biobanking Platform – BBMRI.ch. Available at: Interoperability – Swiss Biobanking Platform (accessed: 15/11/2024).

[3] Further information available at: MIABIS - BBMRI-ERIC (accessed: 15/11/2024).

[4] KIEHNTOPF, M., & KRAWCZAK, M., *Op. Cit*., p. 370.

[5] KIEHNTOPF, M., & KRAWCZAK, M., *Op. Cit*., pp. 370-371.

[6] RUSH, A., BYRNE, J. A., & WATSON, P. H. (2024). Applying Findable, Accessible, Interoperable, and Reusable Principles to Biospecimens and Biobanks. *Biopreservation and Biobanking*.

[7] Available from: https://www.akek.de/biobanken/ (accessed: 06/12/2024).

- Adoption of uniformised Ethics Committees' guidelines for scientific research. Currently, there is the *Best Practice Guide for Research Integrity and Ethics*, from the Austrian Federal Ministry of Education, Science and Research (BMBWF)[8];

- Promoting clear and univocal interpretation of existing legal instruments which greatly impact the biobanking sector, such as Austrian Data Protection Act (*Datenschutzgesetz*, known as the 'DSG'[9]) and the Austrian Research Organisation Act (*Forschungsorganisationsgesetz*, or FOG[10]). This is achieved through the work of the Austrian Data Protection Authority (*Österreichischen Datenschutzbehörde*) and national courts (such as the *Bundesverwaltungsgericht*). Across the EU, the European Data Protection Board also emits guidelines and opinions on the interpretation of EU-issued data protection legislation;

- As other EU countries have done, Austria could adopt a "Biobanking Law", defining the concept of 'biobanks' and 'biobanking activities', thus differentiating from specimen and sample 'collections'. Further information on how other EU countries approach biobanking from a legal perspective can be found in our answer to Question no. 5;

- Producing templates of data sharing and sample (material) sharing agreements Each institution often has their own templates, which are not uniformised in the national context.

1.2. Across Europe:

- EU-level legislation – especially Regulations – governing sample and data sharing: the General Data Protection Regulation (GDPR)[11], Human Tissues and Cells Directive[12], and Substances of Human Origin – SoHO - Regulation[13] are part of a legal framework structuring sample and data transfers within and beyond (imports and exports from/to third countries) the EU/ European Economic Area (EEA);

- EU-level legislation on scientific research with human biological samples: legal acts such as the SoHO Regulation set out principles such as the standards concerning voluntary and unpaid donation of tissues for human application, even in the context of research (Recital 60, *in fine* and Article 54(6)). This sets a uniformised standard for scientific research, which facilitates research within the EU;

- Adopting a "Biobanking Regulation"[14], defining the concept of 'biobanks', 'biobanking activites' which are uniform across Europe. Although this objective may have limited possibility of being pursued in the short or medium term (due to different Member States traditions in approaching the matter of biomedical

[8] Available from: Best Practice Guide for Research Integrity and Ethics (accessed: 01/09/2025).
[9] Bundesgesetz zum Schutz natürlicher Personen bei der Verarbeitung personenbezogener Daten (Datenschutzgesetz – DSG).
[10] Bundesgesetz über allgemeine Angelegenheiten gemäß Art. 89 DSGVO und die Forschungsorganisation (Forschungsorganisationsgesetz – FOG), StF: BGBl. Nr. 341/1981.
[11] General Data Protection Regulation: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The GDPR is a text with EEA relevance. Additionally, it is included in Annex XI of the EEA Agreement (vide §5e).
[12] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
[13] Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC.
[14] KAYE, Jane. "Do we need a uniform regulatory system for biobanks across Europe?." European Journal of Human Genetics 14.2, 2006, pp. 245-248, p. 247.

research and different perceptions in key issues[15]), the current situation in which there is great variability in the definition of these concepts, hinders the interoperability of biobanks[16]. UNIVIE's answer to Question no. 5 thoroughly covers this issue;

- Joining research infrastructures (such as BBMRI-ERIC) alongside fellow biobanking institutions.

Beyond the EU, there are international bodies issuing relevant materials and promoting the accession to Treaties:

- Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997). Austria is not a signatory-State of this Convention.

1.3. Worldwide

- Enactment of binding international treaties governing scientific research and, in particular, research participants' rights: enactment, accession and compliance with existing international treaties and adherence to non-legally binding declarations such as the World Medical Association's Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (last amended in October 2024);

- Enactment of non-binding materials and guidelines, such as the World Health Organization's *Guidance for human genome data collection, access, use and sharing*[17].

Disclaimer: *this commentary aims to provide a summary of the main ethical and legal issues related to the questions put by interested stakeholders and to direct them to the relevant legal provisions that are applicable. It does not, however, preclude from reading the official sources of legislation relating to the subject matters of this document as well as those quoted by the authors and does not constitute legal advice.*

[15] BEIER, Katharina & LENK, Christian. "Biobanking strategies and regulative approaches in the EU: recent perspectives." Journal of Biorepository Science for Applied Medicine, 2015, pp. 69-81, p. 72.
[16] FRANSSON, Martin N., et al. "Toward a common language for biobanking." European Journal of Human Genetics. 23.1, 2015, pp. 22-28.
[17] Available from: Guidance for human genome data collection, access, use and sharing (accessed: 15/01/2025).